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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/787,893 | 04/26/2001 | Marek Naruszewicz | 204742US0PCT | 5028 |

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

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| EXAMINER |
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MARX, IRENE

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,893

Applicant(s)

NARUSZEWICZ, MAREK

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 22, 23, 29, 30 and 36-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 15-17, 22-23, 29-30, and 36-43 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The amendment filed 6/5/03 is acknowledged. Claims 15-17, 22-23, 29-30, and 36-43 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

^{37 and}
Claims [^]41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the designation of cancer as an inflammatory disease, as in claim 37. Cancer is only mentioned in the as-filed specification in the context that “with chronic inflammation there is a risk of an increased ageing process, atherosclerosis and cancer” (page 1, paragraph 5). This statement cannot be equated with cancer being an inflammatory disease.

No basis or support is found in the present specification for the administration of the microorganisms in the manner claim designated to a mammal in an amount “comprising at least 1×10^9 cfu or an equivalent amount of *Lactobacillus plantarum* 299v”. To begin with the specification pertains to “ 1×10^9 CFU/ml”. In addition the administration of “an equivalent amount of *Lactobacillus plantarum* 299v” is not contemplated in the as-filed written disclosure. It is not apparent that “equivalent amounts” are disclosed or addressed.

Furthermore, there is no basis or support found for administration to a mammal in need thereof for the reduction of at least one oxidative stress level; increase in the level of fecal concentration of propionic acid; and/or reduction of adhesion of monocytes to endothelial cells, wherein the mammal has cancer. As noted previously, cancer is only mentioned in the as-filed specification in the context that “with chronic inflammation there is a risk of an increased ageing process, atherosclerosis and cancer” (page 1, paragraph 5). This statement does not proffer clear basis or support for the process as now claimed.

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Therefore, this material raises the issue of new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's statement that cancer is no longer stated to be an inflammatory disease, applicant's attention is directed to claim 37.

In response to the argument that the specification supports claims drawn to administering the claimed microorganism to a mammal in need thereof who **may** have cancer or symptoms thereof, it is noted that "need" in the instant case presumably pertains to the claim preamble, i.e., to certain conditions. That any individual **may** qualify for treatment with *Lactobacillus plantarum* 299v does not mean that "need" can be related to having cancer a now claimed. There is nothing on this record to suggest that the claim designated treatment will be an effective treatment of cancer.

Claims 15-17, 22-23, 29-30, and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-40 are vague and indefinite in the recitation of "comprising at least 1×10^9 cfu or an equivalent amount of *Lactobacillus plantarum* 299v". To begin with the specification pertains to " 1×10^9 CFU/ml". In addition it is unclear what is intended by "or an equivalent amount of *Lactobacillus plantarum* 299v" even when reading the claims in light of the specification. How is "equivalence" determined? It is noted that the process requires viable cells. See also the new matter rejection.

Claims 38-40 are vague, indefinite and confusing in that the units "25 mL/d" are ambiguous. Do applicants mean "per deciliter"? Should applicants mean "per day", it is recommended that the phrase be written out.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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SIX MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
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